

REMARKS

In the Final Office Action dated September 19, 2008, the Examiner rejected claims 1, 2, 8, 11, 3, 15-25, 28, 29, 31-34, and 38-50 under 35 U.S.C § 103(a) as being unpatentable over U.S. Patent No. 6,293,321 to Shinmoto et al. ("Shinmoto") in view of U.S. Patent No. 4,738,668 to Bellotti et al. ("Bellotti '668"); rejected claim 12 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of U.S. Patent No. 4,882,496 to Bellotti et al. ("Bellotti '496"); and rejected claims 26, 27, and 30 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of U.S. Patent No. 4,655,573 to Bellotti et al. ("Bellotti '573").

Applicant respectfully traverses the Examiner's rejection of claims 1, 2, 8, 11, 13, 15-25, 28, 29, 31-34, and 38-50 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668. Applicant submits that the cited references do not disclose or suggest each and every element of independent claims 1, 29, and 33, for example. The Examiner contends that Shinmoto discloses a "first medical device (patient side) with a patient side first connector 2 . . . [a] second medical subsystem 4 [that] comprises a bag side connector 5 . . . [wherein] the apparatus comprises sterilizing means for keeping the interior sterile." (Office Action at 2.) The Examiner concedes, however, that "Shinmoto does not disclose that the apparatus comprises a filter and flow generator that push a sterilizing gas to the interior of the connecting apparatus." (Office Action at 3.) Nevertheless, the Examiner contends that "Bellotti discloses a sterile connection apparatus with an ampoule or disinfectant member 40 in fluid connection with the connector 18 . . . [which] forces a sterilizing gas into the

connector 18 through filter 38 . . . [and a] flow generator [that] is capable of being connected and disconnected to the medical device at different points in the procedure, but does not require disconnection." (Id.) Applicant disagrees. The Examiner further contends that "it would have been obvious for one of ordinary skill in the art to combine the known elements according to known methods to yield the predictable results of a sterile connection apparatus with a gas flow generator with a filter to sterilize the connector." (Office Action at 3.) Applicant further disagrees and submits that the combination of the combined references fails to render the claimed invention unpatentable.

In particular, Applicant submits that Shinmoto and Bellotti '668 do not disclose or suggest "a flow generator for providing said inward flow of gas through the channel, said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion" (emphasis added), as recited in independent claims 1 and 29. As discussed above, the Examiner concedes that Shinmoto does not disclose a flow generator. Moreover, Bellotti '668 does not describe a flow generator capable of supplying gas during disconnection of the first and second connection portions, as required by independent claims 1, 29, and 33. The Examiner contends that "Bellotti does not require that the ampoule be removed, and it is the position of the Examiner that the ampoule is capable of being left in place and providing sterilizing gas at removal as well as at connection. For example, if a syringe is used, the plunger may be depressed only halfway at

connection and then again fully at disconnection." (Office Action at 6.) Applicants disagree.

Bellotti '668 discloses an ampule having "a strong acid and a rupturable cartridge containing an alkali carbonate salt and an alkali hypochlorite salt, to generate chlorine and carbon dioxide for pressurization upon breaking of the cartridge, with the result that the chlorine gas is forced into the interior of the connector for improved antibacterial effect." (Col. 4, lines 18-24.) Bellotti '668 does not disclose that only a portion of the inward flowing gas can be forced into the connection area, while another portion of the gas is held for use at a later time. Nor does Bellotti '668 disclose, either explicitly or implicitly, depressing a plunger halfway at connection and then again fully at disconnection as suggested by the Examiner. In fact, the only indication in Bellotti '668 that something other than an ampoule can force gas into the system states that "[a]lternatively, a syringe, squeeze bulb, or the like may be used." (Col. 4, lines 9-10. Bellotti '668 does not disclose how such a syringe would be used to replace the ampoule, nor does it sufficiently disclose the structure or function of such a syringe in the context of the Bellotti '668 invention. The Examiner has not provided sufficient disclosure in Bellotti '668 or any other prior art reference to support the contention that if syringe was employed in place of the ampoule disclosed in Bellotti '668, half of the gas could be supplied during connection and the other half during disconnection. Bellotti '668 certainly would not enable one of skill in the art to achieve this aspect of the claimed invention, or the invention recited in independent claims 1 and 29 as a whole, even when combined with Shinmoto.

Moreover, Applicant submits that Bellotti '668 teaches away from "supplying said inward flow of gas at least during . . . a disconnection of the first connection portion and the second connection portion," as recited in independent claims 1 and 29. Bellotti '668 discloses that prior to disconnection of the container of spent dialysis solution, any remaining solution is removed from the connection area before a new dialysis solution container is attached. (See, e.g., col. 3, lines 33-61; col. 5, lines 29-31; and col. 7, lines 51-61.) Removal of the remaining solution may be facilitated by passing air into the connection area. (Id.) The removal of this remaining solution is performed "so that the sterilizing action of the antiseptic is not interfered with by the presence of a residue of dialysis solution." (Col. 3, lines 57-61.) As noted above in Bellotti '668, after any remaining solution is removed from the connection area, a container of new dialysis solution is attached to the connection area. Prior to the connection of this new container, the connection area is resterilized. Bellotti '668 discloses that another ampoule containing pressurized chlorine gas is used for this resterilization. (Col. 8, lines 4-8.) Accordingly, Bellotti '668 does not disclose sterilization of the connection area before the container of spent dialysis solution is disconnected so that a clean environment is created during the disconnection of the dialysis container, as required by the claimed invention, and as disclosed in paragraph [0014] on 2 of the published application. To the contrary, Bellotti '668 discloses drainage of the connection area before the disconnection of the spent dialysis solution container and a resterilization of the connection area after the disconnection of the container of spent dialysis solution and after a container of new dialysis solution is attached to the connection area. Thus, while Bellotti '668 discloses an initial sterile environment during connection and a

sterile environment after reconnection of a new dialysis container, Bellotti '668 fails to disclose providing a sterile environment during disconnection, as recited in independent claims 1 and 29.

Applicant further submits that neither Shinmoto nor Bellotti '668 discloses a "filter arranged in said channel for filtering the gas" (emphasis added), as recited in independent claims 1 and 29, for example. The Examiner contends that Bellotti '668 discloses that gas is forced through filter 38 by an ampoule (see Office Action at 3), however, the filter 38 disclosed in Bellotti '668 is located within the ampoule 40 and is not arranged in a channel leading to the connection area, as required by the claimed invention.

Accordingly, for at least all of the reasons discussed above, one of skill in the art would not have achieved the invention recited in independent claims 1 and 29 at the time of the invention based on the cited references, without using improper hindsight. Therefore, independent claims 1 and 29 are allowable over the cited references. Thus, claims 2, 8, 11, 13, 15-25, 28, and 30-32 are allowable over the cited references at least due to their dependence from allowable independent claim 1 and due to their additional recitations of novel subject matter.

Independent method claim 33 is allowable over the cited references, for at least the reasons discussed above regarding claims 1 and 29. Moreover, while the Examiner contends that "the Bellotti apparatus is fully capable of being used during both connection disconnection" (Office Action at 7), Bellotti '668 clearly does not disclose a method including a step of "providing an inward flow of gas into the inner space . . . during connecting the first connection portion and the second connection portion and

disconnecting the first connection portion from the second connection portion” (emphasis added). The claimed method would not have been obvious to one of skill in the art with knowledge of the cited references, without having hindsight knowledge of the present invention. Thus, independent method claim 33 is allowable over the cited references. Moreover, claims 34 and 38-50 are allowable at least due to their respective dependence from allowable independent claim 33.

Applicant also respectfully traverses the Examiner’s rejection of claim 12 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti ‘668 and further in view of Bellotti ‘496. Bellotti ‘496 discloses an “[a]pparatus for disconnecting, sterilizing and making new tubing connection[s].” (Abstract.) The Examiner contends that Bellotti ‘496 discloses “a patient connector apparatus comprising a base 14 that holds connectors, enclosed by lid 12 in order to provide a sterile location for connecting the fluid lines (see FIG2, generally, column 4).” (Office Action at 5.) Bellotti ‘496 does not disclose “a flow generator for providing said inward flow of gas through the channel, said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion” (emphasis added), as recited in independent claim 1. Thus, Applicant submits that Bellotti ‘496 fails to cure the above-mentioned deficiencies of Shinmoto and Bellotti ‘668. Accordingly, independent claim 1 is allowable over the cited references. Thus, claim 12 is allowable at least due to its dependence from allowable independent claim 1 and due to its additional recitations of novel subject matter.

Applicant further traverses the Examiner's rejection of claims 26, 27, and 30 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of Bellotti '573. Bellotti '573 discloses "[a] device [that] automatically uncouples two connectors and forms a new coupling between one of the connectors and another connector in a aseptic manner, without touch contamination from the user." (Abstract.) The Examiner contends that "Bellotti discloses an aseptic tube connection apparatus that comprises an external handle 64 that is rotated by a user to engage gears inside the closed apparatus to move fluid connections in and out of communication with one another (see column 4, lines 41-50)." (Office Action at 5.) Thus, Applicant submits that Bellotti '573 fails to cure the above-mentioned deficiencies of Shinmoto and Bellotti '668. Accordingly, independent claim 1 is allowable over the cited references. Thus, claims 26, 27, and 30 are allowable at least due to their dependence from allowable independent claim 1 and due to their additional recitations of novel subject matter.

Applicant respectfully requests that this Request for Reconsideration After Final under 37 C.F.R. § 1.116 be considered by the Examiner, placing claims 1, 2, 7-34, and 38-50 in condition for allowance. There are no proposed amendments, and thus the application does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships were earlier claimed in the claims as examined. Therefore, this Request for Reconsideration After Final should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the Final Office Action by the Examiner presented some new arguments as to the patentability of Applicants' claims.

It is respectfully submitted that the entry of this Request for Reconsideration After Final would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

In view of the foregoing remarks, Applicant requests the entry of this Request for Reconsideration After Final, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

If a telephone interview will expedite issuance of this application, the Examiner is requested to call the undersigned at (202) 408-4387 to discuss any remaining issues.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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